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EG&G - ROCKY FLATS PLANT
ENVIRONMENTAL MANAGEMENT

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**ROCKY FLATS PLANT
EMD ADMINISTRATION
PROCEDURES MANUAL**

CATEGORY 1

**Manual No.: 3-21000-ADM
Procedure No.. Table of Contents, Rev 3
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Effective Date 04/08/92
Organization Environmental Management**

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PROCUREMENT DOCUMENT CONTROL

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ADMINISTRATIVE PROCEDURE MANUAL

NOT RELATED TO
PLANT SAFETY

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Category 1
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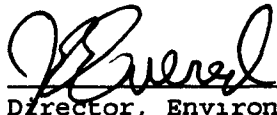
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1.0 PURPOSE

This procedure describes the methods and responsibilities to be used for the control of procurement documents. These controls are intended to ensure that applicable regulatory requirements and design bases are included or referenced in the procurement documents when procuring quality-affecting items or services.

2.0 SCOPE

This procedure applies to all documents in a purchase requisition package for the Environmental Management (EM) Department for the procurement of quality-affecting items or services. This procedure addresses only the quality assurance (QA) requirements. Other guidance, instructions, procedures, and requirements may be established by EM Department management or other Rocky Flats Plant (RFP) organizations.

3.0 DEFINITIONS

- 3.1 **Basic Ordering Agreement (BOA)** - An agreement between RFP procurement organization and a subcontractor that provides for the services from that subcontractor, based upon a previous competitive award. Under a BOA, each statement of work is considered a separately awarded subcontract and terms and conditions must be negotiated. The term BOA is used interchangeably with the term Master Task Agreement (MTA) in this procedure.
- 3.2 **Clarification of Task (COT)** - A written directive provided to the subcontractor holding a specific ongoing subcontract by the EM Department Technical Program manager for clarification of requirements. The requirements must be within the scope of the subcontract and funded under the subcontract for which the COT is issued.

- 3.3 **Invoice** - A bill for services performed or products received, which have been presented by a subcontractor to the RFP procurement organization for approval and payment.
- 3.4 **Procurement** - The responsible designated RFP procurement organization for procurement actions. This incorporates the procurement function.
- 3.5 **Proposal** - A document submitted by a vendor in response to a request for proposal.
- 3.6 **Purchase Order (PO)** - The document issued by RFP procurement organization to a vendor as the end result of a Purchase Requisition. This document contains the specific contractual, technical, and quality requirements for task performance.
- 3.7 **Purchase Requisition (PR) Package** - The initiating document package for procurement of a subcontract or a task under a subcontract. In the context of this document, a Purchase Requisition package includes all required supporting documents.
- 3.8 **Quality Assurance Coordinator (QAC)** - The Division QA coordinator selected by the Division Manager.
- 3.9 **Quality-Affecting Purchase Order** - A PO for an item or service procured under the EM Department and site QA plans. This item or service is quality-related if it affects the quality of the data or compliance with applicable QA requirements.
- 3.10 **Request for Proposal** - A document prepared by the EM Department and the RFP procurement organization which is distributed to potential subcontractors requesting proposals to provide services and/or products for RFP and Department of Energy (DOE).
- 3.11 **Statement of Work (SOW)** - A statement of the item or services to be provided by the vendor or subcontractor. This should include all relevant tasks, deliverables, and requirements. Section 5.2 provides a summary of the minimum requirements (based

on the EM Department QAPD) for the SOW in procurement documentation. This term is used interchangeably with MTA task orders in this procedure.

- 3.12 **Subcontract** - A document or series of documents between RFP procurement organization and a vendor (subcontractor) which require performance of EM Department-related services. A subcontract may only be awarded by the RFP procurement organization and must be executed by both RFP and the subcontractor.
- 3.13 **Subcontractor Representative (STR)** - The specific individual EM Department staff member who has been designated as the responsible technical manager for a specific subcontract or task under a subcontract.
- 3.14 **Task** - A document executed by the RFP procurement organization and a subcontractor which authorizes a specific increment of work to be performed under the auspices of a subcontract.
- 3.15 **Technical Review Board (TRB)** - A panel of RFP personnel who have been selected for review of proposals submitted in response to a request for proposal for competitive selection of a vendor or vendors.
- 3.16 **Justification for Noncompetitive Procurement (JNCP)** - Documents submitted with the PR which justify the requirements for sole source procurement of a service or material.
- 3.17 **Subcontractor Administrator (SA)** - The specific individual Procurement employee who has been designated as the representative of the plant Contracting Officer (CO) and who is responsible for ensuring that all contractual procurement actions are properly executed.
- 3.18 **Organization Conflict of Interest (OCI)** - Documents submitted with the PR which identify any potential conflict of interest situations.

4.0 RESPONSIBILITIES

4.1 The EM Department Environmental Resources and Information Management Division (ERIMD) provides administrative subcontract management under the auspices of the EM Department, and is responsible for:

- 4.1.1 Serving as the central point-of-contact with the RFP procurement organization with regard to aspects of PR package processing to include competitive procurement, processing of new activities under BOAs, and contract/task modifications.
- 4.1.2 Providing timely assistance to EM Department personnel in developing documentation for aspects of PR Packages. ERIMD may prepare the actual PR Package.
- 4.1.3 Assisting EM Department personnel in developing appropriate documentation for EM Department procurement actions. This includes the documentation mandated by this procedure and other plant procedures, instructions, guidance, and documents.
- 4.1.4 Assuring that consistent documentation is utilized for procurement actions.
- 4.1.5 Serving as intermediary on any required conflict resolution between EM Department requisitioner and RFP procurement organization.
- 4.1.6 Maintaining a centralized file pertaining to positive and negative aspects of subcontractor performance for possible use in the future.

4.2 Requisitioner/Subcontractor Technical Representative (STR) is responsible for preparation of technical requirements for PR packages and technical subcontract management for subcontracts under the auspices of the EM Department. The requisitioner and the STR may be different individuals.

Responsibilities include:

- 4.2.1 Informing ERIMD of PR package requirements; providing applicable drawings, specifications, performance requirements, and time frame of service requirements. The requisitioner is responsible for preparation of the PR Package.
- 4.2.2 Reviewing procurement documents which ERIMD prepares for technical adequacy, accuracy, and completeness. Based on this review, the STR will approve ERIMD-prepared procurement documents.
- 4.2.3 Coordinating/monitoring procurement requirements through ERIMD.
- 4.2.4 Complying with QA program requirements, including establishment the applicable QA requirements for the procurement in conjunction with the QAPM.
- 4.2.5 Participating in competitive procurement technical review panels.
- 4.2.6 Providing technical management and oversight of subcontracted functions for which they are assigned responsibility. This includes technical review of products, monitoring of ongoing operations, technical negotiation, developing any required clarification of task documentation in conjunction with ERIMD, and coordinating with subcontractor representatives.
- 4.2.7 Promptly informing ERIMD of problems encountered with regard to subcontract administration.

4.3 EMD Division Managers are responsible for the following:

- 4.3.1 Appointing a Requisitioner/STR who will be responsible for technical oversight of subcontractor-performed operations for the specific contract/task to which they are assigned.
- 4.3.2 Overseeing the activities and implementing the responsibilities of the requisitioner and the STR.
- 4.3.3 Approving PR Packages for adequacy, accuracy, and completeness.

4.4 The EM Department Quality Assurance Program Manager (OAPM), or designee, is responsible for:

- 4.4.1. Reviewing and verifying all potentially quality-related PR Packages for inclusion of quality-related requirements.
- 4.4.2. Assisting the Requisitioner/STR in establishing the applicable QA requirements for the procurement.
- 4.4.3. Reviewing and approving all quality-affecting PR Packages and POs to verify that the quality requirements are met.

5.0 INSTRUCTIONS

5.1 Procurement of Items or Services

- 5.1.1 The Requisitioner/STR provides the information for inclusion during the preparation of the PR package, including:
 - 1. applicable regulatory requirements,
 - 2. design bases,
 - 3. QA requirements, and
 - 4. other requirements necessary to assure that adequate technical and quality

requirements are included or referenced in the PR package. (The selection of appropriate requirements and the detail specified shall reflect the importance, criticality, or complexity of the items or services being procured).

NOTE

Assistance with preparing the QA requirements may be obtained from the QAPM. (See Section 5.2 for basic requirements).

- 5.1.2 ERIMD or the Requisitioner/STR shall prepare the PR package consistent with:
1. this procedure,
 2. applicable instructions, procedures, documents, and requirements established by the EM Department or other RFP organizations.
- 5.1.3 When ERIMD is preparing procurement documentation, they shall ensure that the information provided by the Requisitioner/STR is included in the PR package or obtain the requisitioner/STR's concurrence with any change.
- 5.1.4 The requisitioner/STR(s) shall be provided a copy of the documentation for review and approval (per Section 5.4) prior to issuance of the PR package and to any subsequent revisions of the PR package and associated documentation.
- 5.1.5 ERIMD or the Requisitioner/STR shall obtain the approval of the QAPM or designee (per Section 5.4) prior to issuance of the PR package and to any subsequent revision of the PR package and associated documentation. QAPM approval is based on compliance with the requirements in Section 5.2.

NOTE

Requisitioner/STR(s) should avoid answering vendor questions on competitive procurement, referring such queries to the procurement organization. This should provide for consistent answers to vendor queries.

- 5.1.6 ERIMD shall assist in tracking the request through the approval process, keeping the requisitioner/STR informed, and providing a copy of the completed documentation.
- 5.1.7 For competitive procurement, ERIMD shall assist in formulation of the TRB, provide administrative support during the review process, and prepare TRB recommendations for submission to the RFP procurement organization.
- 5.1.8 If the PR package is acceptable, ERIMD shall forward the PR package to the RFP procurement organization for final processing.

NOTE

Based on the procurement requisition package, a purchase order or contract is prepared by the RFP procurement organization. The finalized document shall be reviewed and approved by the user organization before it is executed. As the single point-of-contact with the RFP procurement organization, ERIMD shall coordinate approval.

- 5.1.9 ERIMD shall provide complete coordination with RFP procurement organization throughout the competitive process.
- 5.1.10 ERIMD shall obtain the requisitioner/STR evaluation of the technical content of any bids and this evaluation shall be the primary basis for assessing technical adequacy of the bid.

- 5.1.11 ERIMD shall obtain input from the STR in answering vendor technical questions and from the QAPM or designee in answering vendor QA questions. This should provide for accurate and consistent answers to vendor queries. Once a contract is established, see Section 5.3 for the interfaces.
- 5.1.12 Upon subcontract/task award, ERIMD shall establish the project as active, establish invoice tracking, and transfer technical management to the Requisitioner/STR.
- 5.1.13 Changes to POs or Contracts shall be completed as described in Section 5.5.
- 5.1.14 PR packages, requests for proposal, POs, and other procurement documents generated by the implementation of this procedure shall be considered QA records and shall be handled in accordance with EM Department QAPD, section 17 and EM Department Procedure 17.01, "QA Records."

5.2 Requirements for the Procurement of Quality-Affecting Items or Services/Content of the Statement of Work (SOW)

NOTE

Sample QA statements for various types of procurements shall be included in the Environmental Management Department Document Preparation Guidance.

- 5.2.1 The procurement documents shall include the following provisions as deemed necessary:
 - 1. Scope of Work - A statement of the work to be performed by the supplier.
 - 2. Technical Requirements - Where necessary, these requirements shall be specified by reference to specific drawings, specifications, codes, standards,

regulations, procedures, or instructions, including revisions thereto, that describe the items or services to be furnished.

3. The procurement documents shall provide for identification of test, inspection (See Appendix 2), and acceptance requirements of the purchaser for monitoring and evaluating the supplier's performance to the extent specified by the organization originating the procurement action.
4. QA Program Requirements - Procurement documents shall require:
 - a) that the supplier have a documented and EMD-approved QA Program, or
 - b) that the supplier follows the EMD QAPD, as well as applicable requirements or implementing documents (e.g., the Quality Assurance Project Plan (QAPjP), Work Plans (WP), and procedures).

A supplier's QA program used as a basis for the procurement shall be part of the contract with the supplier.

- a. The extent of the program required shall depend upon the type and use of the item or service being procured and the instructions of the initiating organization.
- b. The procurement documents shall require the supplier to incorporate appropriate QA program requirements in subtier procurement documents.
- c. The QA program and documents of subcontractors for quality-affecting purchases shall be approved by the requisitioning organization and the EMD QAPM, or designee.

- d. In developing QA requirements for test and other equipment, consideration shall be given to whether proper performance of that equipment can be determined during or after its use (i.e., whether failure or malfunction of the equipment can be detected).
- 5. Rights of Access - At each tier of procurement, the procurement document shall provide for access to the suppliers' facilities and records for inspection (See Appendix 2) by EMD QA and/or Technical Personnel.
- 6. Documentation Requirements - The procurement documents shall identify the documentation required for submission to the Requisitioner/STR.
 - a. A deliverable schedule shall be established.
 - b. The retention times and disposition requirements for required supplier QA records shall be specified in accordance with the information provided by the Requisitioner/STR.
- 7. Spare and Replacement Parts - The procurement documents shall require the identification of appropriate spare and replacement parts or assemblies, and delineation of the technical and quality-related data that is required for ordering parts or assemblies.
 - a. The technical and quality requirements shall be equal to or better than the original item.
 - b. If QA or technical requirements of the original item cannot be determined by the Requisitioner/STR, a documented engineering evaluation shall be

conducted by qualified individuals to establish the requirements. This evaluation shall consider the interchangeability, function, and safety of the item. This evaluation shall be documented.

8. Nonconformances - The procurement documents shall require the supplier to submit nonconformance reports to the RFP procurement organization for disposition and/or approval of nonconformances occurring at the supplier's facility that impact the item(s) being procured. Nonconformances found during receipt inspection shall be processed in accordance with EM Department Procedure 3-21000-ADM 15.01.

NOTE

Resolution of nonconformances requires concurrence of EMD QA.

9. Other applicable documentation.

5.3 Ongoing Contract/Task Operations

- 5.3.1 The Requisitioner/STR manages technical aspects of the contract. This includes vendor contact, issue of COT documents as necessary, review of products and services, and certification of the acceptability of performance.
- 5.3.2 The Requisitioner/STR approves products, services, and invoices submitted.
- 5.3.3 The Requisitioner/STR monitors subcontractor performance, and informs ERIMD of potential problems.

- 5.3.4 ERIMD shall contact the RFP procurement organization as necessary, provide advice as to potential problem resolution, or take other actions necessary to resolve the problem.
- 5.3.5 ERIMD shall inform the Requisitioner/STR and/or obtain the Requisitioner/STR's participation in the problem resolution process.
- 5.3.6 ERIMD shall provide the EMD Director with a monthly report that provides the current status of subcontract activities.
- 5.3.7 ERIMD shall flag potential problems, suspense dates, or subcontract/task expiration dates to the responsible Requisitioner/STR.

5.4 Purchase Requisition Package Review and Approval (see Appendix 1)

- 5.4.1 The PR package and applicable drawings, specifications, catalogs, receiving inspection reports, and other necessary documents that make up the PR package are reviewed for technical adequacy by the Requisitioner/STR and for quality requirements specified by the Requisitioner/STR and/or EMD QA.
- 5.4.2 The reviewers of PR packages shall have access to pertinent information and shall have adequate understanding of the requirements of the procurement documents.
- 5.4.3 ERIMD shall ensure that the following requirements are met:
 - 1. Requisitioner/STR approval is obtained.
 - 2. PO and revision number is indicated on cover page.

3. PR package and revisions(s) are indicated on cover page (Purchase Order and Change Order only).
4. All technical specifications and quality requirements are included as indicated in the corresponding PR package and any supplemental PR package requirements.
5. QA requirements are correctly stated, inspectable, and controllable.
6. Adequate acceptance and rejection criteria are established.
7. Procurement documents have been prepared, reviewed, and approved in accordance with this procedure.
8. The requisitions are reviewed for inclusion of QA and technical requirements, tracked, and, if acceptable, approved and forwarded to the RFP procurement organization for further processing.
9. Changes resulting from bid evaluation or precontract negotiations have been incorporated into the procurement documents.

5.5 Procurement Document Changes

- 5.5.1 Changes to POs/subcontracts shall be initiated by using formal documentation containing the information in Section 5.1.1. The documentation shall specify all changes to terms and conditions of the original PO/subcontract (e.g., quality requirements, technical requirements).
 1. Document any changes in technical or quality requirements.

2. All changes to procurement documents shall be reviewed consistent with Section 5.3.
3. During the review of changes to procurement documents, the following provisions shall be included:
 - a. Appropriate contents are included, as required by Section 5.1.
 - b. Additional or modified design or site investigation criteria is determined.
 - c. Requisitioner/STR performs an analysis of exceptions or changes requested by the supplier and then determines the impact on performance or quality of the item(s) or service(s).

6.0 RECORDS

The records generated by this procedure are the Requisition Package, the Purchase Order Package, the associated review sheets, and the forms in the Appendix to this procedure.

7.0 REFERENCES

1. Environmental Management Department Quality Assurance Program Description (EM Department QAPD).
2. EM Department Quality Procedure 7.01, Control of Purchased Items and Services.
3. EM Department Procedure 3-21000, 15.01, Control of Nonconforming Items.

4. EM Department Procedure 17.01, Quality Assurance Records.
5. Site Quality Assurance Manual, QR-4 and QR-7. Site Procurement Manual.
6. Environmental Management Department Document Preparation Guidance, 3-21000-GD.02.

APPENDIX 1

PROCUREMENT DOCUMENT CHECKLIST

The appropriate Environmental Management Department/Division Technical Reviewer and Quality Coordinator shall perform a review of all Purchase Requisition (PR) Packages, Purchase Orders, and Requests for Proposals to ensure that the applicable technical and quality requirements are included within each procurement package.

1. Are the procurement Documents identified on the face of the document by:
 - a. Charge number yes ☐ no ☐
 - b. QA Level yes ☐ no ☐
 - c. Division ID yes ☐ no ☐
 - d. Other yes ☐ no ☐
2. Are all applicable documents included or referenced:
 - a. Drawings yes ☐ no ☐
 - b. Specifications yes ☐ no ☐
 - c. Receiving Inspection Report (RIR) yes ☐ no ☐
3. Is adequate information provided to include:
 - a. Applicable regulatory requirements yes ☐ no ☐
 - b. Design bases yes ☐ no ☐
 - c. Other requirements to assure that yes ☐ no ☐
adequate technical and quality requirements are included or referenced in the procurement package as required for the above QA Level.

Appendix 1 (continued)

4. Does the procurement document include provisions for:

- a. Scope of work. yes ____ no ____
- b. Technical requirements. yes ____ no ____
- c. Codes, standards, specifications, instructions, procedures, including revisions thereto, that include items/services to be provided. yes ____ no ____
- d. Identification of tests, inspections, and acceptance requirements for monitoring and evaluating the suppliers performance. yes ____ no ____
- e. Is the supplier required to have a QA program? yes ____ no ____
 - 1) Does it address applicable portions of the requirements of the EM Department QAPD and paragraph 5.2.1 (4) of this procedure? yes ____ no ____
 - 2) All of the requirements of the EM Department QAPD and paragraph 5.2.1 (4) of this procedure? yes ____ no ____
- f. Does this document provide for "Right of Access" for each tier of the procurement? yes ____ no ____

Appendix 1 (continued)

- g. Does this document require documentation requirements at all tiers of the procurement to include: yes ____ no ____
- 1) Time of submittal. yes ____ no ____
- 2) Maintenance of specific QA records, retention times, and disposition requirements. yes ____ no ____
- h. Does this document provide for appropriate spare and replacement parts, and the technical and quality-related data required for ordering parts or assemblies? yes ____ no ____
- i Is the supplier required to submit all nonconformance reports, including those occurring at the supplier facility, for disposition and/or approval? yes ____ no ____
- j. Does the supplier appear on the Qualified Suppliers List for the item/service to be supplied. yes ____ no ____

Appendix 1 (continued)

5. Will subcontractor field workers be exposed or potentially be exposed to hazardous materials or wastes? yes ____ no ____
- a. Have provisions been included to assure that all subcontractor workers have received 40 hour OSHA training? yes ____ no ____
- b. Have provisions been included to assure that all subcontractor workers have received an RFP approved baseline physical? yes ____ no ____
- c. Have provisions been included to assure that all supervisors of subcontractor workers have received the RFP 8-hour OSHA Site-Specific Management Training? yes ____ no ____
- d. Have provisions been included to assure that all subcontractor workers have received RFP 24-hour On-The-Job-Training? yes ____ no ____

The above procurement package has been appropriately reviewed in accordance with the requirements of this procedure.

Quality Coordinator

Dept./Div. _____ Date _____

APPENDIX 2

**INSTRUCTION FOR PREPARATION AND USE OF
RECEIVING INSPECTION REPORT FORM**

PURPOSE

The intent of this instruction is to detail the preparation and use of the Receiving Inspection Report Form (RIR).

POLICY

To inspect EM Department procured materials, supplies, and equipment upon their receipt at the Rocky Flats Site to determine conformance to purchase order requirements.

METHOD

A RIR shall be prepared as follows: (Number references are made to space numbers on accompanying form). NOTE: "A" indicates information at time of RIR preparation. "B" indicates information recorded at time of inspection.

- 1A. Item name.
- 2A. Part number, specification number, model number, or other identifying number.
- 3A. Use charge number, followed by fiscal year, followed by sequential number; i.e., 562-92-001.
- 4A. Date RIR is prepared.
- 5A. Name of RIR preparer.
- 6B. Show the entire number as it appears on the purchase order, including the vendor sequence number and the FY.
- 7B. Buyer from the purchase order.
- 8B. Purchase order number from the purchase order.

- 9B. Name of supplier from the purchase order.
- 10B. Date inspection is completed.
- 11B. Where the item is inspected.
- 12B. Clearly printed name of inspector.
- 13B. Quantity ordered from the purchase order.
- 14B. The number of identical items received.
- 15B. Number of items inspected.
- 16B. Number of items found acceptable.
- 17B. Number of items not meeting purchase order requirements. This may be the entire lot or part of the lot.
- 18B. List of those characteristics to be inspected. Each characteristic to be separated from the others by a line drawn from one margin to the other, through the inspector's column. Typical inspection characteristics are shown later in this procedure.
- 19B. When the particular characteristic is inspected, the inspector initials in the adjacent space if acceptable. If not acceptable, the Nonconformance Report number is placed there.
- 20B. List comments. This space may be used to record anomalies in other parameters than those listed in Space 18A.
- 21B. Inspector signs here followed by signature or requisitioning department manager, or designee.



Appendix 2 (continued)
Sample RIR

RECEIVING INSPECTION REPORT

ITEM 1A		PART NO 2A		RIR CHG NO 3A	
PREPARED BY 5A		BUYER 7B		RIR DATE 4A	
PURCHASE ORDER NO 6B		ITEM NO 8B		VENDOR 9B	
INSPECTOR 12B		LOCATION INSPECTED 11B		DATE INSPECTED 10B	
QUANTITY ORDERED 13B	QUANTITY RECEIVED 14B	QUANTITY INSPECTED 15B	QUANTITY ACCEPTED 16B	QUANTITY REJECTED 17B	

REQUIREMENTS		INSPECTOR
18B		19B
COMMENTS 20B		21B <hr/> INSPECTOR <hr/> DEPARTMENT MANAGER

SAMPLE

This is a
CONTROLLED DOCUMENT
EG&G - ROCKY FLATS PLANT
ENVIRONMENTAL MANAGEMENT

This is a **PREPARATION OF INSTRUCTIONS**

3-21000-ADM-05.11

Revision 0

PAGE 1 OF 16

ENVIRONMENTAL MANAGEMENT DEPARTMENT ADMINISTRATIVE PROCEDURE MANUAL

NOT RELATED TO
PLANT SAFETY

Approved By:

Category 1

EFFECTIVE: May 11, 1992

J. Evers
Director, Environmental Management

4/8/92

Date

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856D0138 006

REVIEWED FOR CLASSIFICATION/UCM
By George H. Seabach
Date 4/30/92 unn

1. PURPOSE

To provide an alternative method to procedures for directing Environmental Management Department (EMD) personnel in completion of tasks.

2. SCOPE

This procedure prescribes the steps for developing both Single Use Instructions and Non-quality Related Instructions for both administrative and technical tasks. The contents of this procedure are considered guidance for the Non-quality Related Instructions (i.e., Desk Instructions). The applicable requirements of this procedure are mandatory for quality-related Single Use Instructions (SUI).

3. DEFINITIONS

- 3.1 **Controlled Document Revision Request (CDRR)** - A formal request for revision of an instruction, development of an instruction, or issuance of a manual (see 3-21000-ADM-05.01, Procedure Development).
- 3.2 **Desk Instructions (DI)** - DIs are non-quality related instructions prepared at the discretion of the Responsible EMD Manager. These instructions are prepared to provide assistance to the user rather than to document the steps required to achieve compliance with the QA requirements or technical requirements. The quality of any quality related product produced shall be directly verifiable independent of the existence of the DI. DIs do not replace required quality related procedures.
- 3.3 **History Package** - A file of various drafts of the document, any comment review sheets, and any other associated documents (as described in 3-21000-ADM-05.05, Step 5.8).
- 3.4 **E&WM** - Environmental and Waste Management
- 3.5 **EMD** - Environmental Management Department
- 3.6 **Peer** - See the EMD Document Review Procedure, 3-21000-ADM-05.05, Document Review.

- 3.7 **QAC** - Quality Assurance Coordinator (QAC) is the Division designee who acts as Division representative in the implementation of the EMD Quality Assurance Program Description.
- 3.8 **QAPD** - EMD Quality Assurance Program Description
- 3.9 **QAPM** - EMD Quality Assurance Program Manager
- 3.10 **Procedure Revision Request (PRR)** - See CDRR and Attachment 1.
- 3.11 **Responsible Manager** - The responsible manager is the EMD manager responsible for the task being addressed. For Single Use Instructions (SUIs), the Responsible Manager is the Division Manager or QAPM, as applicable. The designee for the preparation of procedures under 3-21000-ADM-05.02, Procedure Development, is assumed to be designee for instructions as well, unless the letter of designation specifies otherwise.
- 3.12 **Review Executor** - The individual designated by the Responsible Manager to arrange the review of the instruction consistent with Section 5.2 or 5.3.
- 3.13 **RFP** - Rocky Flats Plant
- 3.14 **Single Use Instruction (SUI)** - Instructions for quality related tasks that will be completed less than 10 times.

4. RESPONSIBILITIES

4.1 The responsible manager:

- 1. Identifies the need for instructions, typically based on staff input.
- 2. Arranges for instruction development and review.
- 3. Obtains QAPM concurrence with the instruction.
- 4. Approves instructions.

4.2 The instruction author prepares the draft instruction in compliance with this procedure.

- 4.3 The QAPM reviews all instructions and concurs with valid instructions.
- 4.4 Designated or required reviewers review the instructions consistent with the requirements of this procedure.

5. INSTRUCTIONS

5.1 Instruction Development

- 5.1.1 Instructions shall be developed or existing instructions revised, as necessary, to control activities within the scope of this procedure.

NOTE

For DIs, steps 5.1.2 to 5.1.7 may be completed verbally with no written documentation. A unique developmental identifier for the instruction may be assigned to an instruction prior to completion of steps 5.1.2 to 5.1.7. If the instruction is determined to not be required, the copies are destroyed and the number may be reused.

- 5.1.2 A PRR/CDRR form shall be prepared when individuals identify the need for an instruction or a revision to an instruction. The form shall state the purpose and scope of the proposed instruction or have a draft attached to it.
- 5.1.3 The PRR/CDRR shall be submitted to the QAPM by the responsible manager

NOTE

Steps 5.1.4 and 5.1.5 may be skipped if the Responsible Manager specifies that the suspected duplicate instruction has already been evaluated and found inadequate.

- 5.1.4 The QAPM shall determine if such an instruction already exists. If such an instruction appears to exist, the QAPM shall note the number of the existing instruction on the PRR/CDRR in the justification section and

return the PRR/CDRR to the Responsible Manager.

- 5.1.5 If the PRR/CDRR is returned indicating that it already exists and the Responsible Manager determines, after evaluating the existing instruction that a new instruction is still required, the Responsible Manager may return it to the QAPM for processing after initialing and dating the annotation from step 5.1.4.

NOTE

Evaluation of existing instructions to determine if they are adequate for the intended task (see Step 5.1.5) is at the Responsible Manager's discretion. The only documentation of this evaluation required is specified in Step 5.1.5.

- 5.1.6 The QAPM assigns a unique identifier for the instruction and records this identifier and a unique PRR/CDRR identifier on the PRR/CDRR.
- 5.1.7 The QAPM sends a copy of the PRR/CDRR to the Responsible Manager and, in the case of an SUI, to the EMD records center, per 3-21000-ADM-17.01, Records Management.
- 5.1.8 The author shall draft the instruction using the same format illustrated in Attachment 2 of this procedure. Template files of this format are available from your QAC.

NOTE

For DIs the phrase "NOT QUALITY RELATED" shall be included in the lower right hand corner of the header. This phrase underlined and in italic is required on all DIs. This area is left blank for SUIs.

- 5.1.9 SUIs shall specify the preparation of documentary evidence that activities controlled by the instruction have been conducted in compliance with the instruction

NOTE

Prior to distribution, the author shall obtain a security classification (including Unclassified Nuclear Information) for the instruction, from an authorized classifier.

- 5.1.10 The review and approval process for:
1. SUIs is addressed in Section 5.2.
 2. DIs is addressed in Section 5.3.

5.2 SUI Review and Approval

- 5.2.1 For SUIs the Responsible Manager shall designate a Review Executor.
- 5.2.2 For SUIs the Review Executor shall invoke the EMD Document Review procedure (3-21000-ADM-05.05) to control a review cycle that solicits comments from:
1. The QAPM;
 2. At least one peer;
 3. Each affected RFP organization;
 4. Each affected subcontractor, at the discretion of the Responsible Manager;
 5. Others designated by the Responsible Manager (e.g., Site QA, Health and Safety, Traffic).
- 5.2.3 For SUIs, the QAPM or designee shall review the instruction for compliance with applicable procedures or documents.
- 5.2.4 Disposition of review comments shall be at the discretion of the Responsible Manager. Reviewer concurrence is required if the reviewer's organization is responsible for the activity/technical area at issue.
- 5.2.5 The author shall revise the instruction consistent with the resolutions of comments in

the preceding step.

- 5.2.6 Upon completion of the instruction, the author shall forward a copy of the history package which contains:
- o A copy/original of the completed document review sheets,
 - o A copy/original of each draft which was issued for review, and
 - o A copy/original of the final revision of the instruction to the QAPM.
- 5.2.7 The QAPM shall inspect the history package for compliance with this procedure.
- 5.2.8 If compliant, the QAPM shall sign the instruction on the concurrence line and then submit the instruction to the Responsible Manager for department approval.
- 5.2.9 The Responsible Manager then approves or disapproves the instruction. In either case, the Responsible Manager returns the package to the QAPM.
- 5.2.10 The Responsible Manager shall supply a distribution list for this instruction to the QAPM.
- 5.2.11 The QAPM shall submit the history package to EMD Record Center (per 3-21000-ADM-17.01, Records Management) after making a copy of the approved version of the instruction.
- 5.2.12 The QAPM shall submit the approved version of the instruction copy and distribution list to document control for distribution per 3-21000-ADM-06.01, Document Control.

5.3 DI Review and Approval

- 5.3.1 The Responsible Manager designates a Review

Executor for DIs.

- 5.3.2 The Review Executor arranges a review of the instruction which solicits comments from:
1. The QAPM;
 2. Each affected RFP organization;
 3. Each affected subcontractor, at the discretion of the Responsible Manager;
 4. Others designated by the Responsible Manager (e.g., Site QA, Health and Safety, Traffic).
- 5.3.3 The QAPM or designee shall review the instruction to confirm that the task addressed is not quality related. Any content related comments are considered recommendations and do not require resolution.
- 5.3.4 Resolution and disposition of review comments is at the discretion of the Responsible Manager except as specified in Step 5.3.3. Reviewer concurrence is not required unless the reviewer's organization is responsible for the activity/technical area at issue.
- 5.3.5 The author revises the instruction consistent with the resolutions of comments in the preceding step.
- 5.3.6 Upon completion of this process, the author shall forward a copy of the instruction to the QAPM for concurrence.
- 5.3.7 The QAPM shall sign indicating concurrence if the criteria in step 5.3.3 has been met.
- 5.3.8 The QAPM shall then send the instruction to the Responsible Manager for approval.
- 5.3.9 The Responsible Manager may then approve the instruction.

5.3.10 If the Responsible Manager elects to have the DI issued as a controlled document, the Responsible Manager shall send a copy of the DI and a distribution list to the QAPM for controlled distribution.

5.3.11 Upon receipt of the package addressed in Step 5.3.10, the QAPM shall submit the approved version of the instruction copy to document control for distribution per 3-21000-ADM-06.01, Document Control.

6. RECORDS

The records generated by this procedure are approved SUIs, the history files for SUIs, and approved DIs issued as controlled documents.

7. REFERENCES

- 7.1 EMD Administrative Procedures Manual, 3-21000-ADM-05.05, Document Review procedure
- 7.2 EMD Administrative Procedures Manual, 3-21000-ADM-06.01, Document Control procedure
- 7.3 EMD Administrative Procedures Manual, 3-21000-ADM-17.01, Records Management procedure

ATTACHMENT 1

Procedure Revision Notice (PRR)

PRR (Continuation Sheet)

Refer to 1-11000-PAPG-001 or 1-11000-PAPG-002 for instructions.
PRINT or TYPE all information.Page _____ of _____
PRR No. _____

4. Procedure Number/Revision Level		5. Procedure Title	
6. Page	Step or Section	Proposed Changes	

SAMPLE PROCEDURE REVISION REQUEST (PRR)

Refer to 1-11000-PAPG-001 or 1-11000-PAPG-002 for instructions.
PRINT or TYPE all information (except signatures).Page 1 of _____
PRR No. _____

1. Organization/Plant No./Address		2. Date	3. Cost Center
4. Procedure Number/Revision Level		5. Procedure Title	
6. Procedure Activity Type		7. Duration <input type="checkbox"/> Permanent <input type="checkbox"/> Temporary	8. Change Number
<input type="checkbox"/> New Procedure <input type="checkbox"/> Revision <input type="checkbox"/> Cancellation		<input type="checkbox"/> Temporary <input type="checkbox"/> Permanent	
9. Page	Step or Section	Proposed Changes	
10. Justification (Reason for Change)			
11. Supervisor (signature/initials)			
12. Approver (signature)			
13. Recommended Concerns Organization			
14. Recommended Concerns Organization			
15. Recommended Concerns Organization			
16. Recommended Concerns Organization			
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100. Recommended Concerns Organization			

RP-47948 A (Rev 10/91) Submittal Previous Issues

RP-47948 (Rev 10/91) Submittal Previous Issues

REVIEWED: _____
BY _____
DATE _____

ATTACHMENT 2

Sample Instruction

PREPARATION OF HISTORY FILES

3-21000-MQAI-QA.01
Revision. 0, Draft b
PAGE 1 OF 24

ENVIRONMENTAL MANAGEMENT QUALITY ASSURANCE INSTRUCTION MANUAL

NOT RELATED TO
PLANT SAFETY

Approved By

NOT QUALITY RELATED
EFFECTIVE

Manager EM Quality Assurance Date

1.0 PURPOSE/SCOPE

This instruction is intended to describe how document review history files are prepared for transmittal to Performance Assurance and/or transmission to the EMD record center

2.0 DEFINITIONS/ACRONYMS

2.1 DQA -- Designee of the QAPM
2.2 QAC -- Quality Assurance Coordinator
2.3 QAPM -- Quality Assurance Program Manager
2.4 QAFS -- QAPM Files Secretary
2.5 TER -- Technical Editing Reviewer

3.0 PROCEDURE

RESPONSIBILITY ACTION

3.1	QAPM	Designates DQA
3.2		Transfers document drafts, document reviews, and related information to the DQA.
3.3	DQA	Arranges for maintenance of these future records during the review process (3-21000-ADM-05.05 and any other applicable procedures) in a file system.
3.4		Adds any additional drafts of the document, comment sheets, and other relevant documents to the file system as they are prepared. Items may be removed from the file as necessary to perform required tasks.

ATTACHMENT 2 (Continue)

Sample Instruction

PREPARATION OF HISTORY FILES

3-21000-MQAI-QA.01
Revision. 0, Draft b
PAGE 2 OF 24

RESPONSIBILITY ACTION

- | | |
|---------|---|
| 3 5 DQA | Upon completion of the review and revision process, assembles the history package, consisting of: <ol style="list-style-type: none">1 Each draft version of the document subject to review2 Each comment sheet including documented comment resolution.3 A signed and dated note explaining any missing or mislabeled item, if needed4 Document version for Performance Assurance based external review, external review outside of RFP, or issuance, as applicable.5 Attachment 1 with all applicable sections of the form completed in the QAC Verification Section and the header information except the signatures and the dating of signatures6. EMD Records Transmittal form with all items addressed in package listed except for Attachment 1 Attachment 1 is an internal tracking form and not a QA record. |
| 3 6 | Verifies package adequacy |
| 3 7 | Signs and dates Attachment 1 preparation line |
| 3 8 | Delivers the package to the TER |
| 3 9 TER | Verifies that the items listed in EMD Records Transmittal form (see Step 3 5 item 6) and Attachment 1 (see Step 3 5 item 5) are included in the package. |

ATTACHMENT 2 (Continue)

Sample Instruction

PREPARATION OF HISTORY FILES

3-21000-MQAI-QA.01
Revision. 0, Draft b
PAGE 3 OF 24

<u>RESPONSIBILITY</u>	<u>ACTION</u>
3 10	If Step 3 9 is unsatisfactory, contacts the QAC to resolve discrepancy.
3 11 QAC	Resolves any discrepancies noted in Step 3 9
3 12 TER	Verifies that the Header in Step 3.5 item 5 is consistent with applicable requirements. If requirements are unclear, contacts the DQA for assistance
3.13 TER	Verifies that each comment resolution indicated on the document review sheets are incorporated in the draft document as addressed in Step 3 5 item 2. If incorporation is unclear, contacts the QAC for assistance in clarifying.
3 14	Upon completion of verification of each set of document review sheets, documents this verification by recording commenter's name, review sheet set date, and initialing on Attachment 1. This may be done after Step 3 17.
3 15	If Steps 3 9 to 3.12 were unsatisfactory, contacts the QAC to resolve discrepancy
3 16 QAC	Resolves any discrepancies noted in Steps 3 9 to 3 13
3 17 TER	Documents any outstanding concerns in the comment section
3 18	Upon completion of Steps 3 9 to 3 17, signs and dates the verification section of Attachment 1
3 19	Returns package to QAC
3 20 QAC	Prepares any required transmittal memo(s)
3 21 QAPM	Reviews transmittal memo(s)

ATTACHMENT 2 (Continue)

Sample Instruction

PREPARATION OF HISTORY FILES

3-21000-HQAI-QA.01
Revision. 0, Draft b
PAGE 4 OF 24

<u>RESPONSIBILITY</u>	<u>ACTION</u>
3 22 QAC	Resolves memo(s) contents with the QAPM (see Step 3.21).
3 23	Prepares final transmittal memo(s).
3 24	Provides memo(s) and package (from Step 3 19) to QAPM for approval.
3 25 QAPM	Approves transmittal memo(s) by signing them as appropriate or returns memo(s) and package to the QAC for revision per QAPM direction
3 26 QAC	Removes Attachment 1 from the package for inclusion with the SAIC file copy of the transmittal package only
3 27	Arranges for transmission of the package, then completes the transmission section of Attachment 1
3 28	Delivers Attachment 1 to the QAPM files secretary
3 29 QAFS	Files Attachment 1 with the SAIC file copy of the package (see Step 3.26).

4.0 REFERENCES

3-2100-ADM, 05 05, Document Review

5.0 ATTACHMENTS

Attachment 1 History File Verification Form

ATTACHMENT 2 (Continue)

Sample Instruction

PREPARATION OF HISTORY FILES

3-21000-MQAI-QA.01
Revision. 0, Draft b
PAGE 5 OF 24ATTACHMENT 1
HISTORY FILE VERIFICATION FORM

QAC _____ Phone _____ Page 1 of ____

Document
Title _____

Document No _____ Revision _____ Current Draft _____

QAC VERIFICATION SECTIONPackage Contents (number of items).Drafts (not including final) _____ Final Draft 1
Comment Sheet Packages _____ Other items _____
Pages of EMD Document Transmittal Form _____

QAC Signature _____ Date _____

TER VERIFICATION SECTIONHeader Verified

Format. Yes ___ No ___ Organization Name: Yes ___ No ___

Comment Inclusion Verified.

Commenter	Sheet Date	Verified (initial)
-----------	---------------	-----------------------

ATTACHMENT 2 (Continue)

Sample Instruction

PREPARATION OF HISTORY FILES

3-21000-NQAX-QA.01
Revision. 0, Draft b
PAGE 6 OF 24

ATTACHMENT 1 (Continued)
HISTORY FILE VERIFICATION FORM (Continued)

Document No. _____ Revision _____ Current Draft _____

TER VERIFICATION SECTION (Continued)

Comment Section:

TER Name	Signature	Date
----------	-----------	------

QAC TRANSMISSION SECTION

Transmitted

QAC Signature _____ Date _____

11/11/11



11/11/11

11/11/11

This is a RED Stamp

**CONTROL AND IDENTIFICATION OF
ITEMS, SAMPLES, AND DATA**

3-21000-ADM-08.01

Revision 0

PAGE 1 OF 10

ENVIRONMENTAL MANAGEMENT DEPARTMENT ADMINISTRATIVE PROCEDURE MANUAL

NOT RELATED TO
PLANT SAFETY

Approved By:

Category 1
EFFECTIVE: May 11, 1992



4/8/92

Director, Environmental Management Date

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1 PURPOSE

This procedure establishes the Environmental Management (EM) Department requirements and methods for identifying and controlling items, samples, and data that affect quality. These methods are used to ensure that only correct and accepted items, samples, and data are collected, used or installed.

2 SCOPE

This procedure applies to all EM Department quality related items, samples, and data.

3 DEFINITIONS

- 3.1 Analyte** - Chemical or physical measurement (e.g., chemical concentration, activity, porosity, grain size, pH).
- 3.2 Chain-of-Custody (COC)** - A formalized system of creating an accurate written record to track possession of a sample from collection through analysis to final disposition.
- 3.3 Data** - Measurements, observations, and the required supporting details. This typically includes hard copy or electronic data sheets, analytical reports, technical logbooks, and identity and qualifications of equipment (e.g., serial numbers, calibrations). Procedurally controlled sampling events produce data regardless of whether measurements or samples were obtained.
- 3.4 Field Blank (FB)** - A standard matrix sample, to which no analyte of interest has been added, that is transported to the sampling site and back, to ensure that no contamination is introduced at collection. This sample may be opened near a sampling location or may be unopened, depending on the type of information desired.
- 3.5 Field Data Record (FDR)** - A record completed in the field to record data, observations, and completion of an activity (e.g., data sheet).
- 3.6 Field Duplicate (DUP)** - A split of one sample from a single site taken in the field and submitted to the same laboratory as a separate sample. The results act as an external check on the precision for sampling.

- 3.7 Holding Time** - The maximum time that samples may be held before analysis and still be considered valid.
- 3.8 Item** - An all-inclusive term that is used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system unit, and prototype hardware. This term includes magnetic media and other materials that retain or support data. In this procedure, the term "item" refers only to quality affecting items. Samples and data are items.
- 3.9 Laboratory Blank** - A blank containing a full aliquot of deionized water processed in the same manner as the samples.
- 3.10 Logbook** - A bound notebook that is a quality-related record containing measurements, pertinent information, and data.
- 3.11 Matrix Spike (MS)** - See Spiked Sample.
- 3.12 Method Blank (MB)** - A standard matrix sample to which no analyte of interest has been added that is processed in the same manner as a collected sample to ensure that the method is valid and no contamination is introduced during the analysis.
- 3.13 Preparation Blank** - Water that has been distilled in a tritium distillation apparatus, whose activity is known historically and is used to assure that there is no carry-over or cross-contamination during the distillation step of the sample preparation.
- 3.14 Quality Control (QC)** - The verification of compliance with a prescribed standard. This differs from quality assurance, which addresses and documents the process of achieving quality.
- 3.15 Quality Control Sample** - A sample that is introduced into the process of environmental sampling to monitor the performance of the analytical system.
- 3.16 Reagent Blank (RB)** - A reagent blank is processed in the same manner as the sample to ensure that no contamination is introduced by the reagents.

- 3.17 Rocky Flats Environmental Database RFEDS** - The database where the EM environmental data is stored.
- 3.18 Sample** - Physical evidence collected from a facility or the environment.
- 3.19 Sample Tag/Label** - An identification tag/label attached to each sample that records specific and unique information necessary to identify this sample and provides any required information or warnings. Identification labels are not QA Records.
- 3.20 Spiked Sample (MS)** - A sample to which a known amount of analyte(s) is added and is carried through the complete analytical method.
- 3.21 Split Sample (SPL)** - A representative split of one sample from a single site taken in the field and submitted to different laboratories as separate samples. The results act as an external check on laboratory performance.
- 3.22 Trip Blank (TB)** - A sample to which no analyte of interest has been added and which is introduced into the sampling and analyzing process to determine if sample contamination is due only to sample transport from the field to the laboratory.

4 RESPONSIBILITIES

- 4.1** The Quality Assurance Program Manager (QAPM) is responsible for oversight in implementation of this procedure.
- 4.2** The Responsible Division Manager controls items, samples and data.
- 4.3** The RFEDS Database Administrator controls sample number and location naming conventions.

5 INSTRUCTIONS

5.1 Physical Identification

- 5.1.1** Applicable items shall be uniquely identified and controlled at all times throughout their useful lives. Disposition of items is addressed later in this procedure. Examples of such items include:

- o Reagents
 - o Standard Reference Materials
 - o Air particulate filter papers
 - o Any items with shelf lives
 - o All measurement and test equipment (M&TE)
 - o Environmental samples
 - o Environmental analytical data
- 5.1.2 Work plans or procedures shall require identification of items prior to use.
- 5.1.3 Sample identification shall be placed directly on the sample or sample container and on records traceable to the samples. Each container shall not have redundant labels.
- 5.1.4 Information on sample labels must include the unique sample identifier and requested analysis as specified in Appendix A, and may include:
- 5.1.4.1 Location Number - a unique location code.
 - 5.1.4.2 Indication of whether "physical or chemical treatment" was required and whether or not it was completed (i.e., a "yes" or "no").
 - 5.1.4.3 Date and time - A six-digit number indicating the month, day, and year of collection (e.g., January 13, 1990 is 01-13-90); and a four-digit number indicating the 24-hour time of collection (e.g., 4:29 pm is 1629).
 - 5.1.4.4 Sampler(s) signature or initials.
 - 5.1.4.5 Remarks.
- 5.1.5 Sample labels for SPLs or DUPs shall have the same sample number with a unique identifier added. The original sample shall be identified as "REAL" and any subsample shall be identified as SPL or DUP.
- 5.1.6 All data used on the label shall be entered into an electronic format and provided to RFEDS for tracking and storage.

- 5.1.7 To prevent damage to an item, all methods of identification and/or control shall be compatible with the item to which they are applied. Environmental conditions shall also be taken into account to avoid loss or damage to the label. Special care shall be taken to avoid contamination of instruments and samples when using labels containing adhesives.
- 5.1.8 Document control shall assign unique logbook identifiers for all logbooks containing quality affecting data.
- 5.1.9 The individual to whom a logbook is assigned shall ensure the following information is recorded in the logbook prior to initial use:
 - 5.1.9.1 Logbook identifier
 - 5.1.9.2 Assignee's name
 - 5.1.9.3 Initiation dateLeave a space for completion date at the beginning of the logbook.
- 5.1.10 Photographs taken to enhance field or laboratory work shall be uniquely identified to correlate to logbook entries, Field Data Records (FDRs), or other related documents.

5.2 Inventory

- 5.2.1 All quality affecting items shall be tracked. Such items include:
 - 5.2.1.1 Items requiring special handling, such as samples requiring controlled temperature.
 - 5.2.1.2 Samples required for compliance reporting.
 - 5.2.1.3 Measurement and test equipment.
- 5.2.2 Unique item identifiers shall be recorded. Unique sample numbers shall be recorded in the sample collection logbook and/or FDRs and shall be entered into RFEDS.

- 5.2.3 Measurement data may be recorded directly in logbooks, on FDRs, or other media specified by a procedure.
- 5.2.4 Tracking records for items with a finite shelf life shall include an expiration date. For working solutions, the expiration date may be indicated on the container rather than in separate tracking records.

5.3 Control and Custody

- 5.3.1 Custodians and locations of items shall be designated and tracked (i.e., recorded and maintained current) for all items from acquisition of the item through disposition of the item. Custody may be transferred.
- 5.3.2 A sample is considered to be in an individual's custody if the sample is:
 - 5.3.2.1 In the physical possession of the responsible party, or
 - 5.3.2.2 In one's view after being in one's physical possession, or
 - 5.3.2.3 Secured to either prevent tampering or assure notification of tampering.
 - 5.3.2.4 Laboratory COC procedures shall be reviewed, approved, and verified by the QAPM.
- 5.3.3 The control of samples shall be documented on a Chain-of-Custody (COC) form from the time of collection through all transfers of custody (including analytical labs) until its final disposition/disposal.
- 5.3.4 If a sample under COC is split, a new COC form shall be established for this sample, and the splitting of the original sample shall be documented on both the original COC and on the new COCs.

- 5.3.5 All data used on the field COC must be entered into an electronic format and provided to the RFEDS group for tracking and storage.
- 5.3.6 Data control systems shall:
 - 5.3.6.1 Provide protection of data against damage, loss, or tampering.
 - 5.3.6.2 Provide retrieval of data with identifying information.
 - 5.3.6.3 Ensure data integrity and preclude overwriting, deletion, or loss of raw data.
 - 5.3.6.4 Provide for the revision of data.
- 5.3.7 Logbook entries shall be signed and dated at least once on every page. Entries should be made using permanent waterproof ink.
- 5.3.8 If a logbook is typically used by only one person, then any other individual making an entry into this logbook shall clearly identify their entries.
- 5.3.9 When the logbook or the work is completed, the assignee shall make a final entry into the logbook indicating that this is the final entry, and should reference other related logbooks.
- 5.3.10 Data records acquired under the control of QA procedures are QA records and shall be transmitted to the records center. FDRs shall be transmitted per 5-21000-OPS-FO.02, Transmission of Field QA Records.

5.4 Disposition

- 5.4.1 Procedures or instructions shall be prepared for the disposal of expired items. If an item becomes hazardous after its shelf life has expired (e.g., ether), the procedure shall specify positive safety controls.
- 5.4.2 Data shall be identified and authenticated in accordance with 3-21000-ADM-17.01, Quality Assurance Records Management, prior to distribution to persons other than plant employees.

6 RECORDS

This procedure does not create records in and of itself. Rather the records are created in other procedures.

7 REFERENCES

- 7.1 Environmental Management Department Quality Assurance Program Description, 21000-QAPD.
- 7.2 EMD Administrative Procedure 3-21000-ADM-17.01, Records Management.
- 7.3 EMD Operations Procedure 5-21000-OPS-FO.02, Transmission of Field QA Records.

APPENDIX A

CONVENTION FOR UNIQUE SAMPLE IDENTIFIERS

Unique sample identifiers shall consist of the following fields and allowed values. If there is no applicable code, contact the RFEDS Database Administrator to obtain the appropriate code.

Sample number: XXYYZZZZCC

XX = sample type

AR - air monitoring	SW - surface water
BI - biological/biota	SS - surficial soil
BH - borehole	ST - Storm event
GW - groundwater	TR - soil trench
SD - sediment	YW - surveillance surface water

YY = last two digits of year

ZZZZZ = consecutive number

CC = contract identifier

EB - EBASCO	ST - Stoller
CH - CH2MHill	WC - Woodward Clyde
IT - International Technologies	WS - Weston
RE - Riedel	

Analysis method: AAAA

AAAA - method code or bottle identifier
(Obtain this code from the applicable procedure or datasheet, your supervisor, the Project Manager, or contact RFEDS Database Administrator.)

Field QC code: QQQQ

QQQQ - field quality control code

REAL - actual sample
NONE - no sample taken
DUP - duplicate
ER - equipment rinse
FB - field blank
LR - Lab rinse
MS - matrix spike
MSD - matrix spike duplicate
RNS - rinse
SPL - split
TB - trip blank



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Approved By

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[Signature]
Director, Environmental Management

4/8/92
Date

1.0 PURPOSE

The purpose of this procedure is to describe the methods used to perform inspections of Environmental Management Department (EMD) quality-affecting activities. Inspections are to be accomplished as the work is being conducted to ensure that the work is performed to approved documents by qualified personnel and that work documentation is being properly prepared, approved, and controlled.

2.0 SCOPE

The scope of this procedure encompasses the inspection of activities performed in support of EMD activities. This includes inspection of field operations, data management, and other activities designated by the Quality Assurance Program Manager (QAPM) or the responsible manager. This procedure is required when invoked by either the responsible manager for technical inspections or by the QAPM for Quality Assurance (QA) inspections.

3.0 TERMS/DEFINITIONS

3.1 **Activity** - Drilling, sampling and/or measurement activity, monitoring, and other activities that result in the production of data. An activity typically is work performed by the contractor or a single subcontractor and is discretely unique; i.e., drilling versus biota sampling. Note: this definition was developed to aid in establishing criteria for the separation of Environmental Management Inspection Reports.

3.2 **Checklist** - As used in this procedure is a list of items/activities to be addressed in an inspection.

3.3 **EM** - Environmental Management.

3.4 **EMIR** - Environmental Management Inspection Report.

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- 3.5 **QAA** - Quality Assurance Addendum to the Quality Assurance Project Plan (QAPjP).
- 3.6 **QAC** - Quality Assurance Coordinator.
- 3.7 **QA Inspections** - Inspections performed by the designee of the QAPM per the criteria established by the QAPM.
- 3.8 **QAPM** - Quality Assurance Program Manager.
- 3.9 **QAPjP** - Quality Assurance Project Plan.
- 3.10 **Technical Inspections** - Inspections performed by the responsible manager's designee per the criteria established by the responsible manager.

4.0 RESPONSIBILITIES

NOTE

In the interest of implementing total quality management, the responsible Division Manager may elect to participate in the QA Inspection process. If the Division Manager elects to participate in this process, the Division Manager's designee completes the following activities:

- 1. Develop and review applicable checklists,
- 2. Provide inspectors,
- 3. Implement the inspection program, and
- 4. Schedule and coordinate the inspection program.

The QAPM will still review, approve, and arrange for issuance of the checklists and will still receive copies of all inspection reports.

- 4.1 If the Division Managers elect to participate in the implementation of the QA Inspection program for their Division, they are responsible to designate individuals to implement inspections.
- 4.2 The responsible manager is responsible for supervising the inspectors for Technical Inspections and for coordinating the scheduling with the QAPM for QA Inspections. In addition, each responsible manager may establish other inspections required to implement their responsibilities (Technical Inspection).

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- 4.3 Inspectors are responsible for performing and documenting field inspections in accordance with this procedure.
- 4.4 The EM QAPM is responsible for approving specific inspection checklists and arranging for QA Inspections, arranging for the issuance of a checklist as a controlled document when needed, maintaining the EMIR log, and reviewing all completed EMIRs for areas of quality concern.

5.0 PROCEDURE

5.1 General

- 5.1.1 The responsible Division Manager may elect to implement the QA Inspection program with concurrence and oversight by the QAPM. This requires notification of the QAPM in writing.
- 5.1.2 Responsible Managers may elect to terminate their implementation of the QA Inspection program (see Step 5.1.1) by notifying the QAPM in writing.
- 5.1.3 The responsible Division Managers shall specify the scope of their implementation program in the written notification described in Steps 5.1.1 or 5.1.2.
- 5.1.4 The QAPM shall establish and approve a set of QA Inspection Checklists establishing minimum inspection checklist content requirements.
- 5.1.5 Approved QA Checklists shall be placed under controlled distribution in accordance with 3-21000-ADM-06.01, Document Control. Other inspection checklists may be placed under controlled distribution at the discretion of the responsible manager.
- 5.1.6 The QAPM (for QA Inspections) or responsible manager's designee (for Technical Inspections) shall coordinate with work managers to identify those activities that are in progress.

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- 5.1.7 The QAPM or responsible manager's designee (as applicable) shall specify activities requiring inspection.
- 5.1.8 QA Inspections shall be conducted on a frequency approved by the QAPM. The responsible managers shall establish the schedule for Technical Inspections of EM activities in their area of responsibility. The frequency of Technical Inspections shall be based on past history, risk, complexity, importance, and applicable regulatory requirements.
- 5.1.9 Technical Inspections shall be documented. This documentation is typically recorded on the EM Inspection Report forms (Attachment 1).
- 5.1.10 The QAPM or designee shall assign unique identifiers for each scheduled inspection.
- 5.1.11 Checklists shall be prepared for work procedures requiring inspections.
- 5.1.12 Checklists shall be approved by the QAPM for QA Inspections or by the responsible manager for Technical Inspections.
- 5.1.13 Completed checklists shall be attached to the EMIR and become part of the record of inspection.

5.2 Inspection

- 5.2.1 The inspector shall assemble and/or prepare a checklist based on consideration of the following documents:
- the EM QAPjP (if applicable);
 - the applicable activity-specific QAA; activity-specific work plan, and the work procedures;
 - Environmental Management Inspection Checklist Manual; and
 - other applicable documents.
- The inspector's checklist shall include all applicable items from the Environmental

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Management Inspection Checklist Manual.
Additional checklist items may be added by the
inspector at this time without approvals.

- 5.2.2 The inspector shall conduct the inspection by:
- 5.2.2.1 Verifying that current approved work plans, work procedures, other technical documents are in use.
 - 5.2.2.2 Verifying that current approved and applicable training has been completed.
 - 5.2.2.3 Inspecting the items/activities addressed in the checklists.
 - 5.2.2.4 Documenting the inspection results by:
 - 1. Initialing the inspected items on the checklist(s);
 - 2. Addressing all items of deviations and deficiency on the checklist(s).
 - 3. Authenticating the checklist(s);
 - 5.2.2.5 Notifying the designated individual of observed problem areas within 2 working days. (For QA Inspection the designated individual is the QAPM or designee. For Technical Inspection the designated individual is the responsible manager or designee.)
 - 5.2.2.6 Identifying potential needs for Document Change Notices (DCNs) (see 3-21000-ADM-05.07, Preparation of Document Change Notices) and Nonconformance Reports (NCRs) (see 3-21000-ADM-15.01, Control of Nonconforming Items and Activities);

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and for initiating these documents
when appropriate.

- 5.2.3 The inspector records the unique identifier
 for this inspection on the EMIR.
- 5.2.4 The inspector shall submit a copy of the
 completed EMIR, with completed checklists, to
 the EM QAPM for QA Inspections and to the
 responsible manager for all inspections.
- 5.2.5 The inspector shall transmit the completed
 EMIR in accordance with 5-21000-FOP.02,
 Transmittal of Field QA Records.

6.0 REFERENCES

- 1. Environmental Management Quality Assurance Program
 Description (21000-QAPD)
- 2. Environmental Management Quality Assurance Project Plan
 (21000-QAPJP)
- 3. Environmental Management Inspection Checklist Manual
- 4. Environmental Management Administrative Procedure No. 3-
 21000-ADM 05.07, Preparation of Document Change Notices
- 5. Environmental Management Administrative Procedure No. 3-
 21000-ADM 06.01, Document Control
- 6. Environmental Management Administrative Procedure No. 3-
 21000-ADM 15.01, Control of Nonconforming Items and
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- 7. Environmental Management Operations Procedure No. 5-
 21000-FOP.02, Transmittal of Field QA Records

7.0 ATTACHMENTS

Attachment 1 - EM Inspection Report Form, Part I

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Attachment 1 EM Inspection Report (EMIR) Part I

 <div style="text-align: right; padding-top: 10px;">EMIR No. _____</div> <h3 style="text-align: center; margin-top: 10px;">EM Inspection Report (EMIR)</h3>	
Project Name: _____	
Location: _____	
Activity Description: _____	
Personnel Contacted (include company and title) _____ _____ _____	
References (include Revision/Date) _____ _____ _____	
Inspection Results	
<ul style="list-style-type: none">○ Equipment _____ _____ _____ ○ Deficiencies _____ _____ _____ _____ _____ _____ _____ _____ _____ ○ Summary/Comments _____ _____ _____ _____ _____ _____ _____ _____ _____	SAMPLE
By _____ / _____ / _____ <div style="display: flex; justify-content: space-between; font-size: 0.8em;">Print NameSignatureDate</div>	
Dist Original - Records Center Copies - Project Manager, RPD OC, EMAD OC EM OAPM	

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CONTROL OF MEASURING AND TEST EQUIPMENT

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TITLE:
CONTROL OF MEASURING
AND TEST EQUIPMENT

Approved By


Director, Environmental Management

4/8/92
Date

1.0 PURPOSE

This procedure describes the manner in which measuring and test equipment (M&TE) are controlled for quality.

M&TE are controlled in order to provide equipment and instrument performance within a known and acceptable range. Control of M&TE is achieved through calibrations, measurements, inspections, and testing.

2.0 SCOPE

This procedure applies to all equipment used to make quality affecting measurements or to calibrate devices used to make quality affecting measurements, as specified in the EMD operating procedures for that equipment.

M&TE may include such items as tools, gauges, instruments, equipment used to collect environmental data, and test and inspection equipment. Devices such as rulers, tape measures, levels, chronographs (e.g., wrist or pocket watches) may not require calibration or special controls if normal commercial practices provide adequate accuracy (e.g., traceability to the National Institute of Standards and Technology (NIST)).

3.0 DEFINITIONS

- 3.1 **Accuracy** - The closeness of a measured value to the true value or standard value; may be quantitatively expressed by the uncertainty about the expected value.
- 3.2 **Accuracy and operability checks** - Verification that the M&TE is operating within acceptable norms by checking its performance against a known source. Operability verifies that the instrument is functioning.
- 3.3 **Calibration** - The act of comparing M&TE against a known standard and either documenting the deviation from the standard or correcting to the standard.
- 3.4 **Inspection** - Checking against established standards and procedures.

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- 3.5 **Metrology Organization** - The RFP organization whose primary function involves measurement and includes performing calibrations.
- 3.6 **Precision** - The distribution of repeated measurements about the measurement mean.
- 3.7 **Quality Affecting Measurement** - Any measurement required to ensure protection of health, safety, and the environment, or to demonstrate regulatory compliance.
- 3.8 **Test** - A critical examination, observation, or evaluation for which acceptance criteria are known in advance.
- 3.9 **Uncertainty** - An estimate of the range of values about the measured value in which the true value is believed to exist (e.g., variance). Typically includes errors/deviations related to both accuracy and precision.

4.0 RESPONSIBILITIES

- 4.1 The EM Division Managers, or their designees, are responsible for developing control procedures which identify M&TE items, schedule calibration, specify methods employed for evaluations, training of personnel, and acceptance criteria. The responsible EM Division Manager is responsible for the control and maintenance of any standards possessed by their organizations.
- 4.2 The EM Quality Assurance Program Manager (QAPM) is responsible for assuring that applicable quality specifications, instructions, and procedures are contained in the procedures for control and calibration of M&TE.
- 4.3 The Project Manager is responsible for:
 - 4.3.1 Identifying required M&TE in work plans.
 - 4.3.2 Ensuring that field personnel have received documented training in the use of the M&TE required for the completion of their tasks.
 - 4.3.3 Ensuring that appropriate and calibrated M&TE are available to the personnel completing activities within their area of responsibility.

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4.4 The M&TE user is responsible for the following:

4.4.1 Using certified standards and equipment.

4.4.2 Notifying the responsible manager of out-of-tolerance or discrepancy conditions.

5.0 PROCEDURES

5.1 Identification of M&TE

NOTE

The QAPM may provide assistance to identify applicable standards for M&TE calibration, maintenance, and accuracy and operability checks. Steps 5.1.1 to 5.1.3 may be completed in any order.

5.1.1 The Project Manager shall provide a list to the Division Manager of all M&TE required to complete the activities within their area of responsibility. This list is typically found in the work plan and called the M&TE List.

5.1.2 The Project Manager shall identify the applicable standards for calibration of the equipment identified in Step 5.1.1 and include them on the M&TE List.

5.1.3 The Project Manager shall identify the required maintenance and accuracy and operability tests required for use of the equipment identified in Step 5.1.1 and include these requirements on the M&TE List.

5.1.4 The Project Manager shall identify the acceptable accuracy and precision for the M&TE based on documented requirements, and shall include these requirements on the M&TE List. This list is typically included in the work plan.

5.1.5 The Division Manager shall complete the tasks in Steps 5.1.1 to 5.1.3 for all activities within the Manager's area of responsibility when the activity is not covered by a Project Manager.

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- 5.1.6 The M&TE Lists shall be submitted to the responsible Division Manager (either directly or as part of the work plan) who examines them for adequacy and arranges for revisions as necessary.
- 5.1.7 The Division Manager shall handle the M&TE List as a QA record per 3-21000-ADM-17.01, Records Management.
- 5.1.8 The QAPM shall review the M&TE Lists against existing procedures and documents and resolve any discrepancies with the responsible Manager or the Metrology organization.
- 5.1.9 The QAPM and the Project Manager or Division Manager shall at any time, but at least quarterly, review the M&TE List, procurement, and the schedule for examination of M&TE. Previous examination findings and present or future workloads requiring M&TE shall be assessed in order to provide appropriate equipment that fulfills the acceptance criteria for any particular program.

5.2 Calibration Program

- 5.2.1 The responsible Division Manager shall establish a calibration and maintenance program for the items on the M&TE list for which they are responsible. This program shall include the following:
 - 5.2.1.1 Labeling calibrated equipment with a uniquely numbered label indicating the date the calibration expires and initialed by the individual attaching the label. These labels can be obtained from the Responsible Division Manager or designee. The number of this label shall be noted on the calibration certificate. If this label is added after the calibration, the individual applying the label shall note its number, calibration

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expiration date, and date of application on the certificate and then sign the note. If the calibration label is applied by a vendor, the responsible Division Manager may elect to also affix a RFP label.

5.2.1.2

M&TE calibration certificates and maintenance records which includes the following information:

1. Instrument description and model number.
2. Instrument identification number (typically the serial number).
3. Identification of the traceable standard/source including the accuracy and precision (e.g., standard error at 95 percent confidence level), expiration date of its calibration, and the information identified in items 1 and 2 for the standard/source. For maintenance documentation, this identification is only required if a standard/source is used as part of the maintenance activity.
4. Description of the as-found conditions of the M&TE including accuracy and functional state. Also, formal requirements for notification (and including temporary hold point) if the as-found conditions exceed the tolerances on the M&TE List (see Step 5.1.4). Additional special tests may be needed to establish as found conditions

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for out-of-specification equipment, so calibration should only proceed after authorization from the QAPM.

5. The accuracy and uncertainty after calibration (i.e., the calibrated value) when calibration is performed.
6. Description of any maintenance activity performed. This shall include documentation of any parts replaced and justification for any replacement parts, that are not of the same make and model as the original part.
7. The environmental conditions under which the calibration was performed (e.g., temperature).
8. Special uses, limitations, status, or calibration/maintenance expiration date, when applicable.
9. Any supplementary data needed for accuracy and operability checks.
10. Location and date of installation at RFP, if any. Otherwise, indicate the fate of the M&TE (e.g., field survey instrument controlled by ...).
11. Date and time.
12. Name or initials of the individuals conducting the calibration or maintenance.

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- 5.2.1.3 Calibrations include at least 3 reasonably distributed points on each routinely used scale. Fewer points can be used if the linearity of the instrument is clearly established. At least one point of calibration is required on all scales used to make measurements. Typically the first time M&TE is calibrated the number of points are increased to establish the M&TE performance.
- 5.2.1.4 Separately calibrating portions of an instrument is acceptable if there is technical justification for assuming the calibration would apply to the instrument as a whole. However, calibration of the entire instrument in its functional configuration is preferred.
- 5.2.1.5 The calibration shall be consistent with the planned measurement and projected environments.
- 5.2.1.6 Calibrations, measurements, inspections, and testing shall be conducted at a frequency commensurate with equipment manufacturer's suggestions or occur either at the time of use or on a periodic basis as specified in operational procedures or work plans, whichever is more frequent, except as discussed in Step 5.2.1.7. These calibration intervals shall be conducted in such a manner as to minimize the occurrence of out-of-tolerance conditions.
- 5.2.1.7 Manufacturer's calibration intervals may be changed based on a documented technical evaluation.

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Such an evaluation could be based on the following considerations:

1. Historical data on M&TE's performance in the actual environment in which it is used.
2. The routine use of accuracy and operability checks.
3. The projected amount of use the M&TE has received and the environment in which it occurs.
4. Other technical considerations.

This evaluation shall have the concurrence of the responsible Division Manager, the QAPM, and the Metrology organization.

5.2.1.8 Calibration and maintenance shall be consistent with the standards, applicable guidance, and requirements identified in the M&TE List.

5.2.1.9 Traceable certified standards shall be employed when calibrating, measuring, inspecting, or testing equipment. These standards shall be documented for uncertainty, stability, range, and resolution, according to their intended use. These standards may be maintained by the Metrology Organization, the Responsible Division Manager, or subcontractor's calibration organization.

5.2.1.10 A procedure for identifying and documenting equipment that is out of compliance, damaged, expired,

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lost, or inappropriate for use shall be installed for the EM Department and be consistent with any Level 1 and 2 procedures.

- 5.2.1.11 The M&TE documentation discussed in Step 5.2.1.2 shall be reviewed during or after completion of the calibration or maintenance activity to assure that the as-found conditions are within specification. If the as-found conditions are outside acceptable specifications, a Nonconformance Report (see 3-21000-ADM-15.01, Control of Nonconforming Items and Activities) shall be generated to assess the impact and, when possible, qualify the data collected for "use as is". The intended actions to correct the problem shall also be stated.
- 5.2.1.12 The use of preventive maintenance shall be implemented to maintain continuously acceptable M&TE.
- 5.2.1.13 Records of equipment maintenance shall be documented. If the M&TE is not calibrated prior to use following maintenance, this must either be addressed in an existing procedure or the decision to not calibrate must be formally documented with QAPM concurrence.
- 5.2.1.14 A recall and notification system shall be established to assure the M&TE is appropriately maintained and calibrated.
- 5.2.1.15 The responsible manager should maintain a file or log of each piece of M&TE documenting its maintenance and calibration history for at least 36 months. Where accuracy and operability

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checks are performed, these data should also be included in this file.

- 5.2.1.16 Yearly reviews based on the date maintained per 5.2.2.13 and other sources shall be made to assess the M&TE's performance and reliability. M&TE with poor performance and reliability shall be replaced as soon as practicable.

5.3 Ensuring Conformance

- 5.3.1 Out-of-tolerance criteria shall be established to ensure that measurements made by M&TE and measurement standards that are found to be out-of-tolerance do not adversely affect quality. All out-of-tolerance conditions shall be documented on a label consistent with the operational procedures for the equipment or other equivalent methods.
- 5.3.2 If M&TE is not functioning or potentially malfunctioning, it shall be tagged to indicate that it is out of calibration and segregated where feasible until it can be repaired, if necessary, and recalibrated.
- 5.3.3 If the M&TE does not have a current calibration indicator, it is presumed to be out of calibration.
- 5.3.4 All documentation of control techniques shall be in accordance with procedure 3-21000-ADM-06.01, Document Control.
- 5.3.5 The QAPM shall arrange for QA inspections (per 3-21000-ADM-10.01, Inspection) of the M&TE program at least twice each year.
- 5.3.6 The QAPM shall arrange for a surveillance (per 3-21000-ADM-18.02, Surveillance) of the M&TE program at least once each year.

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5.3.8 The use of M&TE shall be addressed by procedures, which include the following:

1. Clear identification of the M&TE to be used.
2. A requirement for verification of the M&TE prior to usage.
3. Inclusion of any accuracy and operability checks.
4. Clear specification of the required accuracy of the measurement.
5. Specification of any applicable environmental limitations.
6. Documentation of the M&TE used (typically including serial number).

5.3.9 Approval from the RFP metrology organization should be solicited for purchase requisitions and purchase orders for M&TE services.

5.3.10 Calibration adjustments shall be sealed by the calibrating organization and the M&TE shall be presumed to be out of calibration if the seals are lost or broken.

5.4 Controls

5.4.1 Measurement standards should be approved by the Metrology organization and assigned an uncertainty factor and expiration date.

5.4.2 Storage and Transportation

5.4.2.1 Measurement standards and M&TE shall be stored, handled, and transported in a manner that shall not adversely affect the calibration or proper operation of the equipment.

5.4.2.2 All measurement standards and M&TE shall be tested prior to shipment

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to be tested for proper operation. Upon return, the equipment shall be retested.

5.4.2.3 Requests for new M&TE and disposal of old M&TE should be approved by the Metrology organization.

5.4.3 Procedures addressing the calibration of M&TE shall contain the following:

5.4.3.1 Precautions and limitations for the M&TE.

5.4.3.2 Identification of calibration standards to be used in the calibration.

5.4.3.3 Calibration instruction and documentation of performance.

5.4.3.4 Acceptance criteria for each range.

5.4.3.5 Verification review of the calibration documentation by a qualified individual who did not perform the calibration.

5.5 QA Records

5.5.1 A copy of all documentation prepared under this procedure shall be submitted to the EM Department records center per 3-21000-ADM-17.01, Records Management, by the individual who completes this record.

5.5.2 The records maintained by the responsible Division Manager are for field use and are not required to be complete or auditable.

5.5.3 Copies of maintenance and operations manuals for all instruments shall be submitted to the EM Department records center upon receipt of the M&TE. Copies of existing manuals for M&TE shall be submitted to the EM Department records center as soon as practicable.

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5.5.4 The Records Center should be notified to accumulate each year's records for each specific M&TE in a single records package. Records for several similar M&TE may be kept in the same package.

6.0 REFERENCES

1. Environmental Management Procedure 3-21000-ADM-17.01, Records Management.
2. Environmental Management Procedure 3-21000-ADM-06.01, Document Control.
3. Environmental Management Procedure 3-21000-ADM-10.01, Inspection
4. Environmental Management Procedure 3-21000-ADM-15.01, Control of Nonconforming Items and Activities
5. Environmental Management Procedure 3-21000-ADM-18.02, Surveillance

7.0 ATTACHMENTS

None

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Category 1 Organization: Environmental Management

Approved By:

**TITLE:
CORRECTIVE ACTION**


Director DATE 4/8/92
Environmental Management

1.0 PURPOSE

To establish a system for promptly identifying, determining the root cause, and providing corrective action for significant or recurring conditions adverse to quality, or potentially adverse to quality. These conditions may include, but are not limited to, a breakdown of the Rocky Flats Plant (RFP) Environmental Management (EM) QA Program and/or repetitive nonconformances.

2.0 SCOPE

This procedure applies to significant or recurring conditions adverse to quality, which can only be corrected through management intervention, as determined by the Department Director or the QAPM.

3.0 DEFINITIONS

3.1 Condition Adverse to Quality - An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if not corrected, could have a serious effect on safety or effective implementation of the RFP EM Program.

3.2 Corrective Action - Measures taken to rectify conditions that are adverse to quality and, where necessary, to preclude recurrence.

4.0 RESPONSIBILITIES

4.1 EM personnel and EM subcontractor personnel assigned to a quality affecting project or task are responsible for identifying any significant or recurring conditions adverse to quality to the QAPM and/or the EMD Director, and for initiating a Nonconformance Report (NCR), if

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appropriate. EM personnel and EM subcontractor personnel are also responsible for implementing assigned corrective actions.

- 4.2 The EM Department Director, or delegate, is responsible for assigning corrective action responsibility to EM and EM subcontractor personnel if the action involves technical activities.
- 4.3 The Quality Assurance Program Manager (QAPM), or delegate, is responsible for assigning corrective action responsibility to QA personnel, as necessary, and is responsible for corrective action verification.

5.0 PROCEDURE

NOTE

If the space in Attachment 1 is not sufficient to complete the documentation, attach additional sheets. Record the EMD CAR No., the Date, and Page of data on any additional sheets.

5.1 Preparation of a Corrective Action Report

- 5.1.1 If the EMD Director or the QAPM identify a condition adverse to quality, or potentially adverse to quality, they shall initiate a corrective action report (Attachment 1). If the Director determines that immediate actions are necessary, the QAPM and affected technical management shall be informed and the actions implemented.
 - 5.1.1.1 The originator shall complete the header and origination sections of a CAR (see Attachments 1 and 2).
 - 5.1.1.2 All CARs shall be assigned a unique number in the following format: RFP-EM-CAR-XX-YY, where XX is the fiscal year and YY is a unique, sequential number starting with 01. CAR numbers are assigned by the EM QAPM, and the numbers are tracked in a deficiency document tracking system in accordance with EMD procedure addressing trend

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analyses. Until the trend analysis procedure is addressed the QAPM shall establish these numbers.

5.1.1.3 The originator shall also prepare NCRs, unless they already exist (see 3-21000-ADM-15.01, Control of Nonconforming Items).

5.1.2 The QAPM and/or the EMD Department Director review and approve the CAR and then directs its entry into a deficiency document tracking system.

5.1.2.1 If the QAPM determines that the immediate remedial actions identified are inadequate to mitigate the adverse condition, the QAPM shall immediately contact appropriate management to ensure the necessary actions are taken in a timely manner.

5.1.2.2 A copy of the CAR submitted shall be sent to the EMD records center (see 3-21000-ADM-17.01, Records Management).

5.1.2.3 The QAPM investigates and then reviews the proposed CAR and revises as necessary if the deficiency identified justifies issuance of a CAR. The QAPM then approves the CAR.

5.1.2.4 If the QAPM determines that a CAR is not appropriate, the QAPM documents this on the CAR but does not approve it.

5.1.2.5 The QAPM sends copies of the CAR to the originator (if known), EMD Director, and the EMD records center (see 3-21000-ADM-17.01, Records Management).

5.1.3 The QAPM shall assign a response date based on the immediacy of the situation but not to

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exceed 30 days from the initiation date of the CAR. The CAR shall be forwarded to responsible management. Responsible management shall identify the cause and propose appropriate remedial/investigative actions to prevent recurrence or provide a plan describing future actions to resolve the CAR. Responsible management shall sign and date the CAR.

- 5.1.4 The CAR shall then be returned to the QAPM for review of the cause statement and the proposed corrective action.
- 5.1.5 If the QAPM determines the response is unacceptable, the QAPM shall return a copy of the CAR to the responsible manager indicating it is either rejected or requires amendment (CAR item 15). This action will include a memo addressing the basis for not accepting the CAR and recommendations for revision. The Response Due Date shall be revised as appropriate by the QAPM.
 - 5.1.5.1 Upon receipt of a CAR that requires amendment or has been rejected, the responsible manager shall revise the CAR as appropriate and then return it to the QAPM per Step 5.1.4.
 - 5.1.5.2 The documentation generated in Step 5.1.5 are QA records and shall be handled per 3-21000-ADM-17.01, Records Management.
- 5.1.6 After the QAPM's approval of the proposed corrective action and determination of cause, the CAR shall be distributed to a responsible manager. Responsible managers shall notify affected personnel at all levels of the adverse condition(s) regarding lessons to be learned to improve conditions or ways to avoid similar occurrences. Also, the responsible managers shall assign a Corrective Action Implementor to carry out the approved corrective actions.

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- 5.1.7 The designated Corrective Action Implementor, upon receipt of the CAR, shall ensure the QAPM's signed approval of the proposed corrective action prior to implementing the corrective action. The Corrective Action Implementor shall complete the corrective action within the schedule established by the QAPM in consultation with the responsible manager and the EMD Director.
- 5.1.8 If, during the course of implementing the corrective actions, the Corrective Action Implementor discovers that the original response to the CAR was in error or not of sufficient detail, an amended response shall be submitted to the QAPM detailing the new information and projecting the subsequent revised due date.
- 5.1.9 If the required actions cannot be completed by the scheduled due date, an extension request shall be submitted to the QAPM.
 - 5.1.9.1 Extension requests shall be evaluated by the Director or delegate, and the results shall be documented and filed with the Corrective Action Report.
 - 5.1.9.2 The organization requesting extensions shall be notified of extension requests that are approved or denied.
- 5.1.10 After the corrective action has been completed, the CAR shall be signed and dated by the Corrective Action Implementor (CAR item 14).

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- 5.1.11 The CAR shall be returned to the QAPM for verification of completed corrective action and closure of the CAR. This verification shall ensure that applicable actions have been reviewed, implemented, monitored, and revised, if necessary.
 - 5.1.11.1 Verify completion of the corrective action using audit, surveillance, inspections, or management review of the affected activity.
 - 5.1.11.2 If verification of corrective action is unsatisfactory, reissue the CAR in accordance with Step 5.3.1.
 - 5.1.11.3 Document verification of the corrective actions on the CAR form.
- 5.1.12 To close the CAR, the QAPM shall:
 - 5.1.12.1 Review the CAR for completeness and effectiveness of corrective action.
 - 5.1.12.2 If Step 5.1.12.1 is satisfactory, then sign and date the report (in the Verification section [see CAR item 18] of the Evaluation block) and record the date of Closure.
 - 5.1.12.3 If the CAR is closed, distribute, log and file the report as a QA Record in accordance with 3-21000-ADM, 17.01, Records Management.

NOTE

The distribution for a closed CAR is the EM Department Director and EM Division Managers.

- 5.1.12.4 If Step 5.1.11.2 is not satisfactory, issue a memo to the responsible manager to document outstanding concerns and potential resolutions, with a copy to the EMD Director.

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5.2 Failure To Meet Implementation Schedule

- 5.2.1 If the responsible manager fails to meet the required implementation schedule, as adjusted by approved extension requests, the QAPM shall evaluate the impact on data quality and completeness; and any impacts on health, safety, and the environment. The QAPM should consult with the responsible manager and appropriate health, safety, and environment personnel in preparing this evaluation. The QAPM shall present the evaluation to the EMD Director.
- 5.2.2 Distribution of this evaluation shall include the responsible manager and the Manager of Rocky Flats Plant Quality Assurance.

5.3 CAR Status Tracking

- 5.3.1 The CAR (based on the CAR number as described in Step 5.1.1.2) shall be entered into the QA Tracking System. This tracking system shall be used to monitor trends and completion of corrective actions.
- 5.3.2 The unapproved CARs shall be included in the tracking system for use in 3-21000-ADM-18.04, Trending Analyses. No actions or schedule requirements shall be associated with these unapproved CARs. They shall be treated as if they are closed, and shall have less significance in 3-21000-ADM-18.04, Trending Analyses.
- 5.3.3 When repetitive or recurring corrective actions are identified, trending analysis shall determine whether further programmatic corrective action is warranted. Subsequent corrective action shall be the subject of a new separate CAR.

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6.0 REFERENCES

- RFP-EM Quality Assurance Program Description
- 3-21000-ADM-15.01, Control of Nonconforming Items
- 3-21000-ADM-17.01, Records Management
- 3-21000-ADM-18.04, Trending Analysis

7.0 ATTACHMENTS

Attachment 1: EM Project Corrective Action Report Form
Attachment 2: Instructions For Completing CAR


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ATTACHMENT 1 EM PROJECT CORRECTIVE ACTION REPORT FORM

ORIGINATION	 EG&G ROCKY FLATS ENVIRONMENTAL MANAGEMENT DEPARTMENT	EM CAR No _____ Date _____ Audit/Surv No _____ Page <u>1</u> of <u>1</u> Responsible Organization _____ Responsible Manager _____ Project Name _____
	Personnel Contacted _____	
	Requirement: _____	
	Deficiency (Description) _____	
	Discussion and Recommended Action(s) _____	
RESPONSE	Originator Name: _____ Originator Signature: _____ QAPM Name: _____ QAPM Signature/Date: _____ Response Due Date: _____	
	Cause: _____ Remedial/Investigative Action(s) _____ Action(s) to Prevent Recurrence _____ <div style="position: absolute; top: 50%; left: 50%; transform: translate(-50%, -50%) rotate(-15deg); font-size: 100px; opacity: 0.3; pointer-events: none;">SAMPLE</div>	
	Response By: _____ Signature: _____ Date: _____ Approved By (Mgr): _____ Signature: _____ Date: _____	
	RESPONSE Accept _____ Amend _____ Reject _____ ATL/STL/Date: _____ QAPM/Date: _____	
	CORRECTIVE ACTIONS COMPLETED	
	Implementer Signature/Date: _____	
	AMENDED RESPONSE Accept _____ Reject _____ ATL/STL/Date: _____ QAPM/Date: _____	
	VERIFICATION REMARKS _____ Satisfactory _____ Unsatisfactory	
	REF AUDIT/SURVEILLANCE NO: _____ ATL/STL/Date: _____ QAPM/Date: _____	
	DATE OF CAR CLOSURE _____	

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ATTACHMENT 2

INSTRUCTIONS FOR COMPLETING CAR

BLOCK/ ITEM NO	RESPONSIBILITY	INSTRUCTION
<u>Origination</u>		
Header	Originator/ QAPM	Enter assigned CAR number and date Enter audit/surveillance number, if applicable Enter the Responsible Organization, Responsible Manager, and Project Name, if known
1	Originator/ QAPM	Identify any individuals contacted
2	Originator/ QAPM	Identify the applicable requirements being addressed
3	Originator/ QAPM	Describe the deficiency in clear, concise terms Identify specific information relative to condition such as title, numbers, locations, identification, etc
4	Originator/ QAPM	Record additional discussion and recommended actions
5	Originator	Originator prints name and then signs form or records "NA" in both spaces
6	QAPM	If this is a valid CAR, revises above information as necessary, then signs and dates the CAR
7	QAPM	Enter response due date
<u>Response</u>		
8	Responsible Actionee	Identify root cause of deficiency
9	Responsible Actionee	Specifies remedial/investigative action(s)
10	Responsible Actionee	List date(s) for accomplishing action
11	Responsible Actionee	Specify actions needed to prevent/preclude deficiency from occurring in the future

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ATTACHMENT 2 - (continued) INSTRUCTIONS - continued

- | | | |
|-------------------|-------------------------------------|--|
| 12 | Responsible
Actionee | List date(s) for accomplishing action |
| 13 | Responsible
Actionee | Enter name, signature, and date |
| 14 | Responsible
Management | Enter name, signature, and date of the responsible
manager |
| <u>Evaluation</u> | | |
| 15 | QAPM (ATL/STL) | Indicate results of evaluation of response, sign
and date |
| 16 | Corrective
Action
Implementor | Sign and date when corrective actions are complete |
| 17 | QAPM | Indicate results of evaluation of any amended
response, sign and date |
| 18a | QAPM | Indicate results of verification of CAR actions,
reference audit/surveillance conducted, sign and
date |
| 18b | QAPM | Note any pertinent remarks, such as continuation,
other documents, etc |
| 19 | QAPM (ATL/STL) | Reference applicable audit and surveillance, if
any |
| <u>Close-Out</u> | | |
| 20 | QAPM | Enter date CAR closed |




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TITLE.
SURVEILLANCE

Approved By

Director
Environmental Management

4/8/92

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1 PURPOSE

This procedure describes the Environmental Management (EM) Department requirements for surveillance of department and subcontractor activities at the Rocky Flats Plant (RFP). The purpose of surveillance is to evaluate the effectiveness of existing plans, procedures, training, commitment, and other elements of the QA Program.

2 SCOPE

This procedure applies when it is invoked by the QAPM. Surveillance covers evaluation of items, activities, and personnel performing functions that affect the quality of EM Department responsibilities. Subcontractor items, activities, and personnel are specifically included. This procedure may be invoked for the control of supplier evaluations, supplier performance evaluations, or source verifications.

3 TERMS/DEFINITIONS

- 3.1 Surveillance** - Observing to evaluate whether requirements and methods specified in plans, procedures, and drawings provide adequate management control of items, activities, and personnel. A surveillance may determine the status, adequacy, and effectiveness of work activities.
- 3.2 Acceptance Criteria** - Criteria specified in contracts, statements of work, or other binding requirements documents. These criteria are used to evaluate the acceptability of items, processes, data, or services. Compliance with acceptance criteria is established prior to using items, and may be demonstrated by acceptance test procedures.
- 3.3 Effective** - For the purpose of EM Department surveillance, "effective" means that items, activities, or personnel satisfy specified criteria.

4 RESPONSIBILITIES

4.1 The Quality Assurance Program Manager (QAPM) is responsible for the following:

4.1.1 Developing and maintaining a surveillance schedule.

4.1.2 Approving surveillance reports.

4.1.3 Coordinating with EM Department management to schedule surveillances both within the EM Department and subcontractors.

4.1.4 Designating surveillance personnel.

4.2 The Division Quality Assurance Coordinator (QAC) is responsible for the following:

4.2.1 Provide input to surveillance schedules.

4.2.2 Propose technically qualified surveillance personnel with approval of the responsible manager.

4.3 The Surveillance Team Leader is responsible for the following:

4.3.1 Preparing surveillance notices and checklists.

4.3.2 Coordinating the surveillance team's activities.

4.3.3 Submitting the Surveillance Report to the QAPM and transmitting completed surveillance record packages to EMD records center.

Team Leaders may also participate in the surveillance.

4.4 Surveillance Personnel are responsible for the following:

4.4.1 Provide input to surveillance notices, checklists and surveillance reports.

4.4.2 Conducting their portion of the surveillance as directed by the QAPM or Surveillance Team Leader.

4.5 Responsible Managers for the items, activities, and personnel under surveillance are responsible for the following:

4.5.1 Cooperating with surveillance personnel. Surveillance activities will impact work schedules. Cooperation between all parties involved will minimize any short term deleterious impacts and maximize the long term benefits of the surveillance program.

4.5.2 Providing responses to deficiencies specified in the Surveillance Report.

5 INSTRUCTIONS

5.1 SURVEILLANCE SCHEDULE

5.1.1 A schedule of annual surveillance activities shall be prepared and issued by the QAPM. The QAPM shall coordinate with other EM Department management in order to develop the schedule. The QAPM shall also coordinate with designated surveillance personnel to ascertain frequency, agenda and number of surveillances needed to provide adequate coverage of technical activities. Additional unscheduled surveillance activities may be performed at the discretion of the QAPM.

5.1.2 The Surveillance Schedule shall be updated and issued at least annually, and shall reflect the following, as a minimum:

5.1.2.1 Actual surveillance conducted within the year (scheduled and unscheduled).

5.1.2.2 Planned surveillance to be conducted within the next year.

5.1.2.3 Surveillance scope and scheduled date.

5.1.2.4 Authentication by the QAPM, or designee.

5.1.3 The Surveillance Schedule shall be distributed to the EM Department Director, QAPM, Division Managers, designated QACs, and the EM records center. Authenticated Surveillance Schedules are QA Records.

5.1.4 The QAPM shall maintain a log (Attachment 2) to assign unique identification numbers and should maintain the status of surveillance. The number may have the following format: "EMSURV-YY-NO".

5.1.4.1 YY are the last two digits of the calendar year.

5.1.4.2 NO is the next sequential number for this year.

EMSURV-90-22 is the 22nd surveillance done in 1990.

5.2 SURVEILLANCE PERSONNEL

5.2.1 The QAPM shall designate surveillance personnel. Designated personnel shall be listed in the Surveillance Notice (Attachment 1). The surveillance team for a scientific investigation should include both technical and QA representatives, which may be one and the same.

5.2.2 Surveillance personnel shall not be selected from participants in the work being evaluated, and shall not be selected from personnel who report directly to the manager immediately responsible for performing the work.

5.3 SURVEILLANCE CHECKLIST

5.3.1 A Surveillance Checklist (Attachment 3) shall be prepared by the Surveillance Team Leader for each surveillance. The checklist should identify the following:

5.3.1.1 The surveillance identification number.

5.3.1.2 The scope of items, activities, and personnel to be Evaluated.

5.3.1.3 Typical QA Records (i.e., Purchase Orders, Contracts, procedures, and drawings) to be evaluated in the surveillance. (This would be an incomplete list).

5.3.1.4 Name(s) of team members.

- 5.3.2 The surveillance team leader shall transmit the surveillance notice and checklist to the organization at least five working days prior to surveillance.

5.4 SURVEILLANCE OBSERVATIONS AND CONDUCT

- 5.4.1 Significant surveillance observations shall be recorded as Nonconformance Reports. Surveillance team members should keep personal notes of all observations.
- 5.4.2 Surveillance team members should observe whether records are being completed in accordance with applicable procedures, and whether procedures specify records adequate to assure the quality of work and work products.
- 5.4.3 Surveillance team members should observe whether existing work practices and QA Program elements are effective in achieving and assuring both the:
- 5.4.3.1 Quality of work and work products, and
 - 5.4.3.2 Regulatory compliance.
- 5.4.4 Surveillance team members should observe whether elements of the QA Program are unnecessarily complex or burdensome, or produce negative impacts on safety, quality, or environmental protection.
- 5.4.5 Surveillance team members should immediately communicate any concerns observed during the surveillance. Such communication should be expressed verbally to personnel on the scene or to the Responsible Manager, at the discretion of the team member.
- 5.4.6 Nonconformance reports shall be prepared as appropriate.

5.5 DRAFT SURVEILLANCE REPORT

- 5.5.1 After completing the surveillance, team members shall prepare a draft Surveillance Report (cover page format is illustrated in Attachment 4), as described below.

5.5.2 The draft Surveillance Report shall include a statement regarding the effectiveness of the activity, operation, action or work that was observed during the course of the surveillance.

5.5.3 The draft Surveillance Report should describe any unusual, exemplary, and noteworthy practices observed.

5.5.4 The draft Surveillance Report shall identify each document observed and each person interviewed.

5.6 CLOSE OUT MEETING

The Surveillance Team Leader shall schedule a close out meeting with the responsible manager(s) under surveillance. The purpose of the close out meeting is to discuss observations and concerns, clarify issues, correct misunderstandings, and set expectations. The close out meeting should eliminate errors of fact, but need not resolve other disagreements. (Resolution processes are defined elsewhere for Nonconformance Reports).

5.7 FINAL SURVEILLANCE REPORT

5.7.1 The final Surveillance Report shall identify any nonconformance reports issued as a result of the surveillance.

5.7.2 The final Surveillance Report shall be authenticated by the Surveillance Team Leader, and approved by the QAPM.

5.7.3 Copies of the approved Surveillance Report shall be distributed to the appropriate Division Manager(s), the QAC, the QAPM, the EM Department Director, and the EM records center.

6 RECORDS

- 6.1 Surveillance Schedule
- 6.2 Surveillance Report
- 6.3 Non-Conformance Reports
- 6.4 Surveillance Check List
- 6.5 Surveillance Notice
- 6.6 QA Surveillance Log


The team leader shall submit these records, except for the surveillance log, as a package to the EMD Records Center.

7 REFERENCES

- 7.1 EMD Procedure 3-21000-ADM, 15.01, Control of Nonconforming Items.

ATTACHMENT 1

SURVEILLANCE NOTICE FORMAT

 ROCKY FLATS ENVIRONMENTAL MANAGEMENT DEPARTMENT	<div style="text-align: center;">SURVEILLANCE NOTICE</div> <div style="text-align: right;"> Surveillance No. _____ Date _____ </div>
PROJECT/PROGRAM DESCRIPTION _____ _____ _____ _____ _____	
SURVEILLANCE SCOPE. _____ _____ _____ _____ _____ _____	
DOCUMENTS TO BE OBSERVED: _____ _____ _____ _____	
SCHEDULED DATE(S) _____ _____ _____	
SURVEILLANCE TEAM <div style="margin-left: 40px;"> TEAM LEADER _____ TEAM MEMBERS _____ _____ </div>	
<div style="display: flex; justify-content: space-between;"> _____ QA Program Manager _____ Date </div>	

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QA SURVEILLANCE LOG FORM

PAGE ____ OF ____

[illegible]

ATTACHMENT 3

SURVEILLANCE CHECKLIST FORMAT


ROCKY FLATS PLANT
ENVIRONMENTAL MANAGEMENT DEPARTMENT
QAA 2.1 SURVEILLANCE RFP-EM-91-06

No.	Description	Citation*	Observation	Documents Observed*
1 01	Determine if a specific organizational structure has been developed for the activity under review	Site-Wide QAPJP, Section 1 0, Paragraph 1 2		
1 02	Determine if the personnel identified in the organizational structure are the same persons conducting the work for the specified position	Site-Wide QAPJP, Section 1 0, Paragraph 1 2		
1 03	Determine if the subcontractor's organization is specified by the QAA for activity under review			
2 01	Determine if a QAA has been developed and approved for the activity under review	Site-Wide QAPJP, Section 2 0, Paragraph 2 3		
2 02	Verify that all personnel assigned to the task under review have documented evidence of training for their specific function.	Site-Wide QAPJP, Section 2 0, Paragraph 2 4 1; ER QAPD, Section 2 0, Paragraph 2 6		

* Indicate "NA" if not applicable.

ATTACHMENT 4

SURVEILLANCE REPORT FORMAT

 ROCKY FLATS ENVIRONMENTAL MANAGEMENT DEPARTMENT	EMD Surveillance Report	Surveillance Date: _____ Surveillance No.: _____
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Surveillance Subject: _____

Surveillance Scope: _____

Personnel Contacted: _____

Surveillance Results:

- o Executive Summary _____
- o Deficiencies: _____

Surveillance Team:

Team Leader: _____

Team Members: _____

NCRs for deficiencies observed during this surveillance are attached.

_____ QA Program Manager	_____ Date
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